

Notice of Allowability	Application No.	Applicant(s)	
	10/725,373	SCHLOM ET AL.	
	Examiner	Art Unit	
	MARIANNE DIBRINO	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment and terminal disclaimer, both filed 8/5/09.
2. ☒ The allowed claim(s) is/are 47-50,53,54,56 and 60-80.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

/Ram R. Shukla/
 Supervisory Patent Examiner, Art Unit 1644

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DETAILED ACTION

1. Applicant's response filed 8/5/09 is acknowledged and has been entered.
2. The terminal disclaimer filed on 8/5/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,756,038 has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. The said terminal disclaimer filed on 8/5/09 has overcome the prior rejection of record of claims 53, 54, 56 and 66-73 on the ground of nonstatutory obviousness-type double patenting over claims 13-16 of U.S. Patent No. 6,756,038.
4. Applicant's amendment filed 8/5/09 has overcome the prior rejection of record of claims 70-73 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.
5. The prior rejection of record of claims 47-49 and 60-65 as being provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 3 and 11-15 of copending Application No. 11/321,868 is hereby withdrawn due to the cancellation of said claims 3 and 11-15 in the amendment filed 8/3/09 in said copending 11/321,868.

EXAMINER'S AMENDMENT

6. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given by Ms. Rachel L. Mejdreich in interviews on 11/5/09, 11/16/09 and 11/20/09.

7. (a) In the abstract: The abstract has been deleted and replaced with the following:

A nucleic acid molecule encoding an amino acid sequence consisting of an agonist of a MHC class I binding native sequence of CEA having an amino acid substitution and enhanced immunogenicity compared to the native sequence is described. A vector comprising the nucleic acid molecule, host cell comprising the vector and a kit comprising the encoded agonist peptide are also described.

(b) In the specification:

- The phrase "Figure Insert" has been deleted on page 9 at line 22 and replaced with ---Figure 3B:---
- The phrase ---. Figure 3A:--- has been added after "complexes" and before "T2 cells" on page 9 at line 12.
- A period ---.--- has been added after "complexes" on page 9 at line 12.

(c) In the claims:

- In claim 53, the limitation "gene" has been deleted at line 4 (*i.e.*, at part (b) of the claim) and replaced with ---nucleic acid sequence---.
- In claims 63, 64 and 65 the second instance of "wherein the" after the first instance of "wherein the" has been deleted at line 1 in each of the said claims.

(d) The title of the invention has been changed to: Agonist peptides of carcinoembryonic antigen (CEA) and nucleic acid sequences encoding the agonist peptides.

REASONS FOR ALLOWANCE

8. The following is an examiner's statement of reasons for allowance:

- a. Claims 47-50, 53, 54, 56 and 60-80 are pending and are allowable.
- b. The terminal disclaimer filed 8/5/09 over U.S. Patent Serial No. 6,756,038 is acceptable.
- c. The claimed nucleic acid molecule encoding the CEA agonist peptides consisting of SEQ ID NO: 2, 3, 4 or 5, the kit comprising the said encoded peptides, vector comprising the said nucleic acid molecule, and host cell comprising said vector are not taught or suggested by the prior art.
- d. Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1644